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Substitute for form 1449A and B/PTO		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/528,463
		Filing Date	March 21, 2005
		First Named Inventor	Chantal Guillemette
		Art Unit	1634
		Examiner Name	Amanda Marie Shaw
Sheet 1 of 5	Attorney Docket Number	6013-118US	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
OK		US 6,395,481 B1	05/28/2002	Di Rienzo et al.	
		US 2002016293 A1	02/07/2002	Ratain Mark J et al.	
		US 02/0115097 A1	08/22/2002	Rienzo et al.	
		US 2002/0061518 A1	05/23/2002	Penny et al.	
		US 6,528,260 B1	03/04/2003	Blumenfeld et al.	
		US 5589504	12/31/1996	Dannenberg et al.	

FOREIGN PATENT DOCUMENTS					
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		Country Code3 - Number4 - Kind Code5 (if known)			
OK		WO 02/48400 A	06/20/2002	Ando Yu-Uichi et al.	
		EP 1352970	10/15/2003	Hasegawa et al.	
		WO 01/79230	10/25/2001	Chew et al.	
		WO 00/06776	02/10/2000	Galvin et al.	
		WO 99/57322	11/11/1999	Penny et al.	
		WO 02/053770	07/11/2002	Manns et al.	
		JP 02/085066	03/26/1990	Yamamoto	
		WO 02/06523	01/24/2002	Acuna et al.	
		WO 97/32042	09/04/1997	Burchell, Brian	
		WO 2004/027088 A3	04/01/2004	Guillemette, Chantal	
		WO 2002/18554	03/07/2002	Wei et al.	
		WO 96/01127	01/18/1996	Ratain M. et al.	
		WO 01/80896	11/01/2001	Ratain, M. et al.	
		WO 03/013536	02/20/2003	Heinrich et al.	
		WO92/12987	08/06/1992	Owens et al.	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
OK		DOUGLAS A.P. et al., 1978, "Paracetamol (acetaminophen) kinetics in patients with Gilbert's syndrome" Europe J Clin Pharmacol, 13:209-212	
		BRODER S. et al., 2002, "The human genome" Pharmacogenomics: The Search for Individual Therapies, pages 292-295	

Examiner Signature	<i>Amanda Shaw</i>	Date Considered	11/20/06
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<input checked="" type="checkbox"/>	WOOLLEY A.T. et al., 2000, "Direct haplotyping of kilobase-size DNA using carbon nanotube probes", Nature Biotechnology, 18: 760-763	
<input type="checkbox"/>	MACKLON A.F. et al., 1979, "Gilbert's Syndrome and Drug Metabolism", Clinical Pharmacokinetics, 4 :223-232	
<input type="checkbox"/>	ANDO Y. et al., 2002, "Polymorphisms of UDP-Glucuronosyltransferase and Pharmacokinetics of Irinotecan", Therapeutic Drug Monitoring, 24: 111-116	
<input type="checkbox"/>	ANDO Y. et al., 2000, "Polymorphisms of UDP-Glucuronosyltransferase Gene and Irinotecan Toxicity: A Pharmacogenetic Analysis", Cancer Research, 60: 6921-6926	
<input type="checkbox"/>	ANDO Y. et al., 1998, "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of Irinotecan", Annals of Oncology, 9: 845-847	
<input type="checkbox"/>	VOGEL A. et al., 2001, "Genetic Link of Hepatocellular Carcinoma with Polymorphisms of the UDP-Glucuronosyltransferase UGT1A7 Gene", Gastroenterology, 121: 1136-1144	
<input type="checkbox"/>	BEAULIEU M. et al., 1996, "Isolation and Characterization of a Novel cDNA Encoding a Human UDP-Glucuronosyltransferase Active on C ₁₉ Steroids", The Journal of Biological Chemistry, 271: 22855-22862	
<input type="checkbox"/>	BOSMA P. et al., 1994, "Presence of an additional TA in the TATAA box of B-UGT, correlates with Gilbert syndrome", Hepatology, 20:680	
<input type="checkbox"/>	ALBERT C. et al., 1999, "The Monkey and Human Uridine Diphosphate-Glucuronosyltransferase UGT1A9, Expressed in Steroid Target Tissues, Are Estrogen-Conjugating Enzymes", Endocrinology, 140: 3292-3302	
<input type="checkbox"/>	KIHARA C. et al., 2001, "Prediction of Sensitivity of Esophageal Tumors to Adjuvant Chemotherapy by cDNA Microarray Analysis of Gene-Expression Profiles", Cancer Research, 61:6474-6479	
<input type="checkbox"/>	CIOTTI M. et al., 1997, "Genetic Defects at the UGT1 Locus Associated With Crigler-Najjar Type I Disease, Including a Prenatal Diagnosis", American Journal of Medical Genetics, 68:173-178	
<input type="checkbox"/>	FAUCHER M. et al., 2002, "Founder TIGR/myocilin mutations for glaucoma in the Québec population", Human Molecular Genetics, 11:2077-2090	

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OK		GAGNÉ J.-F. et al. "Common Human UGT1A Polymorphisms and the Altered Metabolism of Irinotecan Active Metabolite 7-Ethyl-10-hydroxycamptothecin", <i>Molecular Pharmacology</i> , 62: 608-617	
↓		GONG Q.-H. et al., 2001, "Thirteen UDPglucuronosyltransferase genes are encoded at the human UGT1 gene complex locus", <i>Pharmacogenetics</i> , 11:357-368	
↓		GUILLEMETTE C. et al., 2000, "Structural Heterogeneity at the UDP-Glucuronosyltransferase 1 locus: functional consequences of three novel missense mutations in the human UGT1A7 gene", <i>Pharmacogenetics</i> , 10: 629-644	
↓		GUILLEMETTE C. et al., 2001, "Association of Genetic Polymorphisms in UGT1A1 with Breast Cancer and Plasma Hormone Levels", <i>Cancer Epidemiology, Biomarkers & Prevention</i> , 10: 711-714	
↓		ZEMBUTSU H. et al., 2002, "Genome-wide cDNA Microarray Screening to Correlate Gene Expression Profiles with Sensitivity of 85 Human Cancer Xenografts to Anticancer Drugs", <i>Cancer Research</i> , 62:518-527	
↓		OWENS I.S. et al., 1995, « Gene structure at the human UGT1 locus creates diversity in isozyme structure, substrate specificity and regulation", <i>Progress in Nucleic Acid Research and Molecular Biology</i> , 51:305-338	
↓		INNOCENTI F. et al., 2001, "Pharmacogenetics of Anticancer Agents: Lessons from Amonafide and Irinotecan", <i>Drug Metabolism and Disposition</i> , 29:596-600	
↓		VENTER J.C. et al., 2001 "The sequence of the human genome", <i>Science</i> , 291:1304-1351	
↓		RAMIREZ J. et al., 2002, "In Vitro Characterization of Hepatic Flavopiridol Metabolism using Human Liver Microsomes and Recombinant UGT Enzymes", <i>Pharmaceutical Research</i> , 19: 588-594	
↓		MCCARTHY J.J., 2002, "Turning SNPs into useful markers of drug response" <i>Pharmacogenomics : The search for individual therapies</i> , pages 35-55	
↓		RITTER J.K. et al., 1992, "A Novel Complex Locus UGT1 Encodes Human Bilirubin, Phenol, and Other UDP-Glucuronosyltransferase Isozymes with Identical Carboxyl Termini", <i>The Journal of Biological Chemistry</i> 267: 3257-3261	
↓		KUHN J.G., 1998, "Pharmacology of Irinotecan", <i>Oncology</i> , 12 :39-42	

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OK		IYER L. et al., 2002, "UGT1A1*28 polymorphism as a determinant of Irinotecan disposition and toxicity", The Pharmacogenomics Journal, 2: 43-47	
		IYER L. et al., 1998, "Genetic predisposition to the metabolism of Irinotecan (CPT-11): Role of Uridine Diphosphate Glucuronosyltransferase Isoform 1A1 in the Glucuronidation of its Active Metabolite (SN-38) in Human Liver Microsomes", Journal of Clinical Investigation, 101:847-854	
		SALTZ L.B. et al., 2000, "Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer", The New England Journal of Medicine, 343:905-914	
		MACKENZIE P.I., 2000, "Identification of Uridine Diphosphate glucuronosyltransferases Involved in the metabolism and clearance of mycophenolic acid", Therapeutic Drug Monitoring, 22: 10-13	
		ANDO M. et al., 2002, "Genetic Polymorphisms of the UDP-glucuronosyltransferase 1A7 Gene and Irinotecan Toxicity in Japanese Cancer Patients", Japanese Journal of Cancer Research, 93: 591-597	
		MONAGHAN G. et al., 1996, "Genetic variation in bilirubin UDP-glucuronosyltransferase gene promoter and Gilbert's syndrome", Lancet, 347:578-581	
		CARULLI N. et al., 1976, "Alteration of drug metabolism in Gilbert's syndrome", Gut, 17: 581-587	
		MACKENZIE P.I. et al., 1997, "The UDP glycosyltransferase gene superfamily: recommended nomenclature update based on evolutionary divergence" Pharmacogenetics, 7:255-269	
		BOSMA P.J. et al., 1994, "Bilirubin UDP-glucuronosyltransferase 1 is the Only Relevant Bilirubin Glucuronidating Isoform in Man", The Journal of Biological Chemistry, 269: 17960-17964	
		BOSMA P.J. et al., 1995, "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome", The New England Journal of Medicine, 333: 1171-1175	
		HERMAN R.J. et al., 1994, "Disposition of Lorazepam in Gilbert's Syndrome: Effects of Fasting, Feeding, and Enterohepatic Circulation.", Journal of Clinical Pharmacology, 34:978-984	
		MEECH R. and Mackenzie P.I., 1997, "Structure and function of uridine diphosphate glucuronosyltransferases", Clinical and experimental pharmacology and physiology, 24: 907-915	

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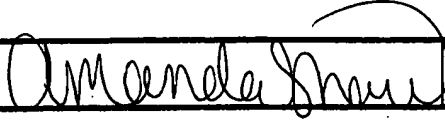
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OK	MEECH R. and Mackenzie P.I., 1997, «UDP-Glucuronosyltransferase, the Role of the Amino Terminus in Dimerization», The Journal of Biological Chemistry, 272: 26913-26917
	BRODER S. et al., 2002, "The human genome" Pharmacogenomics: The Search for Individual Therapies, pages 9-34
	DAN S. et al., 2002, "An Integrated Database of Chemosensitivity to 55 Anticancer Drugs and Gene Expression Profiles of 39 Human Cancer Cell Lines", Cancer Research, 62:1139-1147
	SIMONEN R.L. et al., 2002, "Familial aggregation of physical activity levels in the Québec family study", Medicine and Science in Sports and Exercise, 34:1137-1142
	DE MORAIS S.M.F. et al., 1992, "Decreased Glucuronidation and Increased Bioactivation of Acetaminophen in Gilbert's Syndrome », Gastroenterology; 102 :577-586
	TUKEY R.H. et al., 2000, "Human UDP-Glucuronosyltransferases : Metabolism, Expression, and Disease" Annual Review of Pharmacology and Toxicology, 40: 581-616
	WASSERMAN E. et al., 1997, « Severe CPT-11 toxicity in patients with Gilbert's syndrome : Two case reports », Annals of Oncology, 8 :1049-1051
	DUTTON G.J., 1980, "Glucuronidation of Drugs and Other Compounds; Part I: Glucuronidation, glucuronides, and Studies on UDPGlucuronyltransferase In Vitro", CRC Press, Boca Raton, FL, pages 3-21

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